Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132642

3.1 Date of Submission

08/23/2013

OCT 0 3 2013

3.2 Sponsor Identification

Beijing Libeier Bio-Engineering Institute Co., Ltd.
100, 6th Kechuang Street, Economic And Technological Development Area East,
Beijing, 100176, China.

Establishment Registration Number: Not yet registered

Contact Person: Jenny Jiang
Position: Overseas Specialist
Tel: +86 10 67895577 ext. 8226
Fax: +86 10 67857129
Email: jenny@libeier.com

3.3 Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

3.4 Proposed Devices Identification

Proposed Device Name: Locking Plate System
Proposed Device Common Name: Bone Plates and Bone Screws

Regulatory Information of Plates:
Classification Name: Plate, Fixation, Bone
Common Name: Bone Plates
Class: Class II
Product Code: HRS
Regulation Number: 21 CFR 888.3030
Review Panel: Orthopedic

Regulatory Information of Screws:
Classification Name: Screw, Fixation, Bone
Common Name: Bone Screws
Class: Class II
Product Code: HWC
Regulation Number: 21 CFR 888.3040
Review Panel: Orthopedic

Intended Use Statement:

Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur tibia and fibula.

3.5 Device Description

The proposed products, Locking Plate System, contain (1) locking plates (LPs) with various specifications, (2) locking screws with various specifications and (3) various specific instruments. Locking Plates are the plates that made of Titanium. The limited-contact design of LPs reduces plate-to-bone contact, thus limiting vascular trauma. The screws are available in three kinds, which are 3.5mm Hexagonal Locking Screws with hexagonal interface, 3.5mm Stardrive Locking Screws with Torx interface, and 5.0mm Locking Screws with hexagonal interface. There are various instruments specific to the proposed device intend for completing the surgery.

3.6 Predicate Device Identification

Predicate Device 1

510(k) Number
K101400

Predicate Device Name
Locking Compression Plate

Manufacturer
Changzhou Orthmed Medical Instrument Co., Ltd

Predicate Device 2

510(k) Number
K100721

Predicate Device Name
Locking Bone Screw

Manufacturer
Changzhou Orthmed Medical Instrument Co., Ltd

3.7 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a) ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates.
b) ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws.
c) ISO 17665-1:2006 Sterilization of health care products- Moist heat, Part 1: Requirements for the development, validation and routing control of a sterilization process for medical devices.

3.8 Clinical Testing Conclusion

No clinical study is included in this submission.

3.9 Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device 1	Predicate Device 2
Product Code	HRS	HRS	/
	HWC	/	HWC
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	/
	21 CFR 888.3040	/	21 CFR 888.3040
Class	Class 2	Class 2	Class 2
Intended Use	Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur tibia and fibula.	Locking Compression Plate can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.	Locking Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.
Material	Plate: Titanium	Plate: Titanium	/
	Locking Screw: Titanium alloy	/	Locking Screw: Titanium alloy

How supplied	Non-Sterile	Non-Sterile	Non-Sterile
Single Use	Yes	Yes	Yes
Sterile	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.
Performance	Static and Dynamic Performance tested per ASTM F382 Torsional, Driving Torque and Pull out strength tested per ASTM F543.	Static and Dynamic Performance tested per ASTM F382	Torsional, Driving Torque and Pull out strength tested per ASTM F543.

Differences in intended use, material and performance between the proposed and predicate device have been discussed and address. The proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Beijing Libeier Bio-Engineering Institute Company, Limited
% Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K132642
Trade/Device Name: Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 23, 2013
Received: August 26, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K132642

Device Name: Locking Plate System

Indications for Use:

Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur tibia and fibula.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices